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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR              | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------------------|---------------------|------------------|
| 09/936,566   | 09/14/2001  | Naoki Tsuchiya                    | Q66152              | 8705             |
| 7590 11/03/2004  |             |                                   |                     |                  |
| Sughrue Mion Zinn<br>Macpeak & Seas<br>Suite<br>2100 Pennsylvania Avenue NW<br>Washington, DC 20037-3213 |             | EXAMINER<br>STOCKTON, LAURA LYNNE |                     |                  |
|  |             | ART UNIT PAPER NUMBER             |                     |                  |
|  |             | 1626                              |                     |                  |
| DATE MAILED: 11/03/2004  |             |                                   |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 09/936,566               | TSUCHIYA ET AL.     |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Laura L. Stockton, Ph.D. | 1626                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on September 15, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Claims 22-42 are pending in the application.

### *Continued Prosecution Application*

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2004 has been entered.

### *Claim Objections*

Claims 41 and 42 are objected to under 37 CFR 1.75 as being a substantial duplicate of the claims from which they depend. When two claims in an application are duplicates or else are so close in content that

they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, the G variable representing "SO<sub>2</sub>" lacks antecedent basis from claim 22. See claim 38 for same (depends from claims 29 and 31).

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 19, 21-23, 26-30, 35, 37 and 38 of copending Application No. 09/743,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in application '483 differ only by generic description of the

products. See, for example, claim 18 in application '483 and especially compound 444 in Table 18 on page 33. The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a human chymase inhibitor).

One skilled in the art would thus be motivated to prepare products embraced by application '483 to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as human chymase inhibitors. The instant claimed products would have been suggested and therefore obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Response to Arguments*

Applicants' arguments filed September 15, 2004 have been fully considered. In regard to the rejection of the claims under an obviousness-type double patenting rejection, Applicants state that they will hold the rejection in abeyance until allowable subject matter is indicated in one of the two applications.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 33 and 35-42 are rejected under 35 U.S.C. 102(b) as being anticipated by:

b) Nicolai et al. {Journal of Medicinal Chemistry (1993), 36(9), pages 1175-1187} – see, for example, Tables IV, V and VI on pages 1181, 1182 and 1183, respectively, compounds 7a, 7b, 7c, etc.;

c) Bru-Magniez et al. {U.S. Pat. 5,021,443} – see, for example, Example 63 in column 29;

d) Bru-Magniez et al. {U.S. Pat. 5,124,336} – see, for example, Example 59 in column 41; or

e) Bru-Magniez et al. {U.S. Pat. 5,128,359} – see, for example, Example 64 in column 41.

Each of the above cited prior art disclose products embraced by the instant claims.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 33 and 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. {U.S. Pat. 5,021,443}, Bru-Magniez et al. {U.S. Pat. 5,124,336} and Bru-Magniez et al. {U.S. Pat. 5,128,359}, each taken alone or in combination with each other when similar utilities are asserted.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim benzimidazole products. Bru-Magniez et al. '443 (columns 1, 2 and 11 ; or Example 63 in column 29), Bru-Magniez et al. '336 (columns 1, 2, 11 and 12 ; or Example 59 in column 41) and Bru-Magniez et al. '359 (columns 1, 2, 11 and 12 ; or Example 64 in column 41) each teach benzimidazole products which are either structurally the

same as (see above 102 rejections) or structurally similar to the instant claimed products.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between some of the products of the prior art and the products instantly claimed is that the instant claimed products are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed products derives from the expectation that structurally similar products would possess similar activity (e.g., thromboxane receptor antagonist – TXA<sub>2</sub>).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would have thromboxane receptor antagonist properties and which would be

useful in treating diseases/disorders such as myocardial infarction, angina pectoris, pulmonary embolism, asthma, bronchitis, etc. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

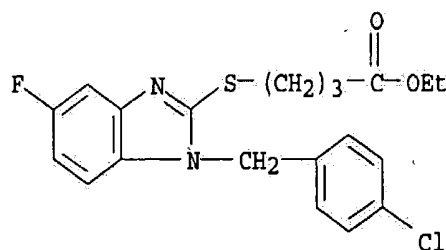
### *Response to Arguments*

Applicants' arguments filed September 15, 2004 have been fully considered. In regard to the rejection of the claims under 35 USC §§ 102(b) and 103, Applicants argue that the compound claims have been amended to exclude the embodiment wherein the group  $-NR^4$  can be contained in the alkaline or alkenylene group between atoms in the substituents substituting the substituents B. Applicants further argue that the proviso has been amended to clarify that it is reciting the case that is excluded.

All of Applicants' arguments have been considered but have not been found persuasive. The instant claimed compounds are anticipated

and found to have been obvious over the above cited references. See, for example, compound 10b (CA Registry No. 136122-57-1- shown below) on page 1182 in Nicolai et al.

RN 136122-57-1 CAPLUS  
CN Butanoic acid, 4-[[1-[(4-chlorophenyl)methyl]-5-fluoro-1H-benzimidazol-2-yl]thio]-, ethyl ester (9CI) (CA INDEX NAME)



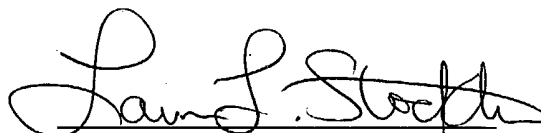
Compound 10b is embraced by instant claim 31 when X<sup>1</sup> is halogen (e.g., fluorine); X<sup>2</sup> is hydrogen; B is an unsubstituted C<sub>1-6</sub> normal alkylene group (e.g., propylene); E is -COOR<sup>4</sup>; R<sup>4</sup> is an unsubstituted C<sub>1-6</sub> normal alkylene group (e.g., ethylene); G is an unsubstituted C<sub>1-6</sub> normal alkylene group (e.g., methylene); J is a halogen substituted C<sub>4-10</sub> aryl group (e.g., 4-chlorophenyl); and M is sulfur. The amendment to the definition of variable B and the proviso at the end of the claim do not circumvent this compound of 10b in Nicolai et al. nor other compounds

in this reference and the other above cited prior art references. The rejection is deemed proper and therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written in a cursive style.

Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

November 1, 2004